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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|---|-------------|----------------------|--------------------------|------------------|
| 10/075,743  | 02/14/2002  | Royce Johnson        | VAC.700                  | 1606             |
| 7590  | 12/16/2004  |                      |                          |                  |
| Kinetic Concepts, Inc.<br>P.O. Box 659508<br>San Antonio, TX 78265-9508 |             |                      |                          |                  |
|   |             |                      | EXAMINER<br>LEWIS, KIM M |                  |
|   |             |                      | ART UNIT<br>3743         | PAPER NUMBER     |

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/075,743

Applicant(s)

JOHNSON ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-9 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-5,9 and 18 is/are allowed.
- 6) ☒ Claim(s) 13-16 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Detailed Action.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/04 has been entered.
2. As requested in the submission, claims 2, 3, 7 and 13 have been amended and claims 4 and 10-12 have been cancelled.
3. Claims 2, 3, 5-9 and 13-18 are pending in the instant application..

### ***Claim Objections***

4. Applicant is advised that should claim 14 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Suggestions***

5. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13, line 4, "bioabsorbable cell-growth" should read --bioabsorbable or includable cell-growth-- for language continuity.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 16, the phrase "the substrate" lacks proper antecedent basis and the examiner is not able to ascertain whether or not the substrate is the pad or a separate element being claimed. Thus, the metes and bounds of the claim cannot be determined.

The applicant should note that where the metes and bounds of a claim are indefinite, it is improper to base a rejection on speculation as to the meaning of the claim. *In re Steele*, 305 F.2d 858, 134 USPQ 292 (CCPA 1962).

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***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/05873 ("Lina et al.") in view of U.S. Patent Application Publication 2003/0077311 A1 ("Vyakarnam et al.").

As regards claim 13, Lina et al. disclose all features of the claimed invention including a porous foamed pad (36), inherently highly reticulated, shaped to conform to a wound (page 8, last paragraph) and formed of a includable cell-growth enhancing matrix, an air-tight seal (wound cover 43) adhered to the skin and/or pad (page 8, 2nd full paragraph), and a negative pressure source (vacuum pump 84) in fluid communication with the pad (page 9, 1<sup>st</sup> full paragraph).

As to the biocompatibility of the pad, since the pad can be placed on or within a wound cavity, the pad is inherently biocompatible. Also, on page 7, starting with the 3<sup>rd</sup>

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full paragraph, Lina et al. disclose the pad as being constructed from open cell polyurethane or polyether foam, both of which is biocompatible.

As to the removability of the air-tight seal (wound cover) from the pad, the examiner contends that the disclosed acrylic adhesive is capable of being removably attached to the pad in the same manner that it is removably attached to the skin.

Vyakarnam et al., however, disclose that it known to apply bioabsorbable polymer foams to various areas of the body in order to promote tissue regeneration. Further disclosed is the use of a ceramic particles or fibers in combination with the foam in order to reinforce the foam such that the foam is strengthened so as to be structurally compatible with cancellous bone (para. 0034).

It would have been obvious to one having ordinary skill in the art to substitute the pad of Lina et al. for a pad constructed from the foam material of Vyakarnam et al. in order to promote tissue regeneration.

As regards claim 14 and 15, Lina et al. disclose that the pad is connected via hoses (37, 38) to a canister (19) and that the canister is connected to the pump. As can be read the last line on page 7, the hoses are preferably made from medical grade PVC tube. This tubing is inherently flexible.

As to claim 6, Lina et al. disclose that the canister is placed within recess (18) and can be removed therefrom (page 13, 2<sup>nd</sup> full paragraph).

### ***Allowable Subject Matter***

11. Claims 2, 3, 5-9 and 18 are allowed.

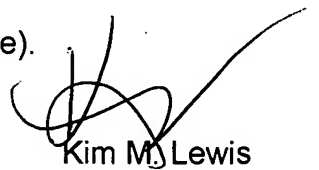
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12. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis  
Primary Examiner  
Art Unit 3743

kml  
December 7, 2004